IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

CIPLA USA, INC., Plaintiff, v. IPSEN BIOPHARMACEUTICALS, INC., Defendant.	C.A. No. 22-552-GBW

MEMORANDUM ORDER

This action stems from a dispute regarding alleged violations of the Lanham Act, 15 U.S.C. § 1125(a), as well as other related state-law claims. *See* D.I. 1. On June 3, 2022, Defendant Ipsen Biopharmaceuticals ("Ipsen") filed a Motion, under Federal Rules of Civil Procedure 12(b)(1) and 12(b)(6), to dismiss Plaintiff Cipla USA, Inc.'s ("Cipla") Complaint. D.I. 16. The parties briefed the issues. *See, e.g.*, D.I. 17; D.I. 21; D.I. 23. On March 1, 2023, Magistrate Judge Fallon issued a Report and Recommendation (the "Report") recommending that the Court deny Ipsen's Motion to Dismiss (the "Motion"). D.I. 64. Ipsen filed objections to the Report on March 15, 2023, D.I. 65, and Cipla filed its response to the objections on March 29, 2023. D.I. 67.

The Court has reviewed the Report, the objections and the response thereto, and has considered *de novo* the parties' briefing and supporting documents related to Ipsen's Motion. *See, e.g.*, 28 U.S.C. § 636(b)(l); FED. R. CIV. P. 72(b)(3); *Brown v. Astrue*, 649 F.3d 193, 195 (3d Cir. 2011). For the reasons set forth below, Ipsen's objections to the Report are **OVERRULED** and the Report's recommendations are **ADOPTED**.

I. STANDARD OF REVIEW

In reviewing the Report, the Court must "make a *de novo* determination of those portions of the report or specified proposed findings or recommendations to which objection is made." 28 U.S.C. § 636(b)(1)(C). The Court may "accept, reject, or modify, in whole or in part" the Magistrate Judge's findings or recommendations. *Id.* As to those portions to which no objections have been made, the Court must "satisfy itself that there is no clear error on the face of the record in order to accept the recommendation." FED. R. CIV. P. 72(b) Advisory Committee Notes; *see Henderson v. Carlson*, 812 F.2d 874, 878 (3d Cir. 1987) (explaining the district court's responsibility "to afford some level of review" when no objections have been made).

II. BACKGROUND[1]

On April 27, 2022, Cipla filed its Complaint, D.I. 1, alleging violations of the Lanham Act and Delaware state law against Ipsen. Ipsen manufactures medical products, including Somatuline® Depot, a drug injection with Lanreotide Acetate as its active ingredient. D.I. 1 ¶ 1. Somatuline® Depot entered the market in 2007 and for many years was the only Lanreotide Acetate injection approved by the U.S. Food and Drug Administration ("FDA"). *Id.* That is, until December 17, 2021, when the FDA approved a Lanreotide Acetate injection product manufactured by InvaGen Pharmaceuticals, Inc., an affiliate of Cipla ("InvaGen's Product"). *Id.* ¶ 2. InvaGen licenses its product for distribution by Cipla. *Id.* The Complaint alleges that, following the FDA approval of InvaGen's Product, "Ipsen has repeatedly made false and/or misleading statement about Cipla and [InvaGen's Product] to Cipla's customers and providers (clinics)[,]" unfairly harming Cipla in the market. D.I. 1 ¶ 5.

[1] The Court writes for the benefit of the parties and assumes their familiarity with this action.

III. DISCUSSION

As discussed in greater detail both in the Report and below, the Medicare Statute, 42 U.S.C. § 1395w-3a(j)(1), does not preclude judicial review in this case. Furthermore, Cipla has adequately pled facts sufficient to state the claims made in the Complaint. As such, the Report is **ADOPTED**, and Ipsen's Motion is denied.

A. Legal Standard

To state a claim on which relief can be granted, a complaint must contain "a short and plain statement of the claim showing that the pleader is entitled to relief . . . ." FED. R. CIV. P. 8(a)(2). Such a claim must plausibly suggest "facts sufficient to 'draw the reasonable inference that the defendant is liable for the misconduct alleged.'" *Doe v. Princeton Univ.*, 30 F.4th 335, 342 (3d Cir. 2022) (quoting *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009)) (citing *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 557 (2007)). "A claim is facially plausible 'when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.'" *Klotz v. Celentano Stadtmauer & Walentowicz LLP*, 991 F.3d 458, 462 (3d Cir. 2021) (quoting *Iqbal*, 556 U.S. at 678). However, the Court will "'disregard legal conclusions and recitals of the elements of a cause of action supported by mere conclusory statements.'" *Princeton Univ.*, 30 F.4th at 342 (citation omitted).

"'The issue is not whether a plaintiff will ultimately prevail but whether the claimant is entitled to offer evidence to support the claims.'" *Pinnavaia v. Celotex Asbestos Settlement Tr.*, 271 F. Supp. 3d 705, 708 (D. Del. 2017) (quoting *In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1420 (3d Cir. 1997)), *aff'd*, 2018 WL 11446482 (3d Cir. Apr. 6, 2018). "A motion to dismiss 'may be granted only if, accepting all well-pleaded allegations in the complaint as true, and viewing them in the light most favorable to plaintiff, plaintiff is not entitled to relief.'"

McCrone v. Acme Markets, 561 F. App'x 169, 172 (3d Cir. 2014) (quoting *Burlington Coat Factory*, 114 F.3d at 1420).

B. The Medicare Statute Does Not Preclude Judicial Review of Counts I-V

Ipsen moves to dismiss all counts, arguing that Cipla's claims are expressly barred by the Medicare statute, 42 U.S.C. § 1395w-3a(j)(1), which states that "[t]here shall be no administrative or judicial review under section 1395ff of this title, section 1395*oo* of this title, or otherwise, of—

(1) determinations of payment amounts under this section, including the assignment of National Drug Codes to billing and payment codes[.]"

42 U.S.C. § 1395w-3a(j)(1).

In its argument, Ipsen characterizes Cipla's allegations as Ipsen making false statements about InvaGen's Product and, specifically, statements about (1) whether Cipla's product belongs in the same Healthcare Common Procedure Coding System (HCPCS) code as Ipsen's product, Somatuline® Depot, and (2) whether the products are therapeutically equivalent or generic versions of each other. D.I. 17 at 8-9; D.I. 64 at 2-3; D.I. 65 at 1. Ipsen then argues that, for this Court to find whether Ipsen made false or misleading claims about the proper HCPCS code, this Court must "interpret and apply the provisions of the Medicare Average Sales Price (ASP) statute and implementing [sic] agency guidance regarding the assignment of drug products to HCPCS codes." D.I. 65 at 2. *See also* D.I. 17 at 8. 42 U.S.C. § 1395w-3a(j)(1) states that "[t]here shall be no administrative or judicial review" of "determinations of payment amounts . . . including the assignment of National Drug Codes to billing and payment codes[.]" Therefore, Ipsen reasons, Cipla's claims are precluded because, for the Court to make a determination on whether Ipsen made false or misleading claims, the Court would have to determine whether

InvaGen's product belong in the same HCPCS code as Somatuline® Depot. D.I. 65 at 1.

This Court agrees with the Report's reasoning—the Complaint does not seek review of HCPCS code assignments, nor do Cipla's claims require the Court to "make HCPCS coding determinations in the first instance." D.I. 64 at 5. The Complaint alleges, for example, that on or before February 24, 2022, Ipsen "distributed a 'Notice Regarding Somatuline® Depot and Cipla's Lanreotide Acetate Product' to providers and wholesaler distributors in the marketplace for purchasing Lanreotide Acetate products." D.I. 1 ¶ 47. The notice allegedly made several statements, including "Use of J1930 for Cipla's product may lead to payment delays, reversals, and denials" and "Cipla's Lanreotide Acetate Product is not reimbursable under HCPCS billing and payment code J1930." *Id.* ¶ 47(c)-(d). The Complaint asserts that these statements are false and misleading for reasons other than the Centers for Medicare & Medicaid Services ("CMS") mislabeling the product. For example, with respect to the latter statement regarding reimbursement of InvaGen's Product under payment code J1930, Cipla asserts that "[t]his statement is false and/or misleading, as the statement wrongly suggests that HCPCS codes affect coverage determinations" and "wrongly suggests that CMS has made a determination that payment code J1930 cannot be used for Cipla's Lanreotide Acetate Product" on or before February 2022, when CMS did not release coding decisions on InvaGen's Product until July 6, 2022. *Id.* ¶ 47(d); D.I. 33. The Court does not need to make a determination on the coding to determine whether Ipsen's statements at the time were false and/or misleading.

Accordingly, having reviewed the record *de novo*, the Court agrees with the Report's conclusion that Cipla's claims are not preempted by the Medicare statute. Thus, Ipsen's objections to the Report are overruled.

C. The Lanham Act Claim I Is Not Precluded

Ipsen next asserts that Cipla's claim under the Lanham Act is also precluded because "a Lanham Act claim cannot be used as a vehicle to seek judicial resolution of a complicated regulatory issue where the regulatory scheme itself lacks a private right of action." D.I. 65 at 5. A Lanham Act claim is precluded when the cause of action "would require a court to make determinations about the safety, legality, and classification of new drugs that are more properly within the exclusive purview of the FDA." *Hi-Tech Pharms., Inc. v. Hodges Consulting, Inc.*, 230 F. Supp. 3d 1323, 1330 (N.D. Ga. Dec. 13, 2016) (citing *POM Wonderful LLC v. Coca-Cola Co.*, 573 U.S. 102, 115 (2014)). Here, the Court agrees with the Report that Cipla's claims are focused on the "competitive harm caused by Ipsen's statements about the proper HCPCS code for InvaGen's Product and how it could impact the customers' ability to receive reimbursement." D.I. 64 at 9. As addressed above, these claims do not require the Court to determine whether CMS properly coded the product, or whether the competing products are therapeutically equivalent. *See supra* § II.B; *see also* D.I. 64 at 9. Instead, "the issue is whether Ipsen misled Cipla's customers by effectively making HCPCS code determinations for InvaGen's Product while the matter is still under agency review." D.I. 64 at 9 (citing D.I. 1 ¶¶ 5, 47). Further, this Court agrees that "the complaint does not require the court to usurp the FDA's authority by making a therapeutic equivalence determination because Cipla never claimed InvaGen's Product is therapeutically equivalent to Somatuline® Depot." *Id.*

Accordingly, having reviewed the record *de novo*, the Court agrees with the Report's conclusion that Count I is not precluded. Thus, Ipsen's objections to the Report are overruled.

D. Plaintiff Has Properly Pled a Lanham Act Claim

Ipsen also alleges that Cipla failed to properly plead a claim under Section 43(a) of the

Lanham Act. In order to establish a Lanham Act violation, Cipla must show:

> 1) that the defendant has made false or misleading statements as to his own product [ ];
>
> 2) that there is actual deception or at least a tendency to deceive a substantial portion of the intended audience;
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> 3) that the deception is material in that it is likely to influence purchasing decisions;
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> 4) that the advertised goods traveled in interstate commerce; and
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> 5) that there is a likelihood of injury to the plaintiff in terms of declining sales, loss of good will, etc."

Warner-Lambert Co. v. Breathasure, Inc., 204 F.3d 87, 91-92 (3d Cir. 2000). Cipla must plead this with "sufficiently detailed allegations regarding the nature of the alleged falsehood to allow defendant to make a proper defense." *Robert Bosch LLC v. Pylon Mfg. Corp.*, 632 F. Supp. 2d 362, 365 (D. Del. 2009) (internal citations and quotation marks omitted).

Ipsen argues that the alleged statements do not constitute "commercial advertising" and that "activities associated with lobbying the government, communicating with federal agencies, and filing APA lawsuits are directly protected by the *Noerr-Pennington* doctrine." D.I. 17 at 12-13. This Court agrees with the Report's reasoning that the Complaint properly alleges "false or misleading statements about InvaGen's product" to customers and providers, and that merely repeating the same statements in communications with federal agencies or for the purpose of filing APA lawsuits does not "immunize Ipsen from liability under the Lanham Act." D.I. 64 at 11 (citing *Caldron, Inc. v. Advanced Measurement & Analysis Grp., Inc.*, 515 F. Supp. 565, 574 (W.D. Pa. 2007)).

Regarding the alleged misrepresentations about the HCPCS coding status and therapeutic equivalence, Ipsen argues that those are "not actionable because they are not statements of fact." D.I. 65 at 7. However, this Court agrees with the Report's reasoning that "[t]he alleged

misrepresentations identified in Cipla's complaint fairly imply a factual basis." D.I. 64 at 12. The Court concludes that "[Ipsen's] statements constitute 'verifiably false statements of fact'—as opposed to mere opinion or puffery." *Shure Inc. v. Clearone, Inc.*, C.A. No. 19-1343-RGA-CJB, 2020 WL 2839294, at *7 (D. Del. June 1, 2020), *report and recommendation adopted* C.A. No. 19-1343-RGA-CJB, 2020 WL 8258362 (D. Del. June 18, 2020). Ipsen's alleged representations "regarding the proper HCPCS code for InvaGen's Product and assertions that InvaGen's Product is not reimbursable under another HCPCS code could reasonably give Cipla's customers the impression that Ipsen was describing actual facts." D.I. 64 at 12 (citing D.I. 1 ¶47). Thus, Cipla "plausibly suggest[s] facts sufficient to draw the reasonable inference that the defendant is liable for the misconduct alleged" required to survive a motion to dismiss. *Princeton Univ.*, 30 F.4th at 342-43 (internal citation and quotations omitted).

Next, Ipsen objects to the Report because it applies the Rule 8(a) pleading standard. D.I. 65 at 8. The Report, in a footnote, states that "Ipsen confirms it 'ha[s] not involved Rule 9(b)'s pleading standards'" and, thus, "the court evaluates the sufficiency under Rule 8(a)." D.I. 64 at 13 n.5 (quoting D.I. 23 at 7 n.6). Ipsen asserts that this was a misreading of its footnote in the reply brief, and that when it said "the defendant had not invoked Rule 9(b)'s pleading standards[,]" Ipsen was referring to "the defendant in the case *discussed in the footnote*." D.I. 65 at 8 (quoting D.I. 23 at 7 n.6) (emphasis in original). But the only case cited in the footnote is *Registered Agent Sols., Inc. v. Corp. Serv. Co.*, C.A. No. 21-786-SB, 2022 WL 911253, at *1 (D. Del. Mar. 28, 2022). D.I. 23 at 7 n.6. And in *Registered Agent Sols., Inc.*, the defendant, Corporation Service Company, did argue for the application of Rule 9(b) in its opening brief in support of its motion to dismiss. *Registered Agent Sols., Inc. v. Corp. Serv. Co.*, C.A. No. 21-786-SB, D.I. 24 at 9-10 (D. Del. Aug. 16, 2021). Alternatively, Ipsen could have been referring

to the case *Shure v. ClearOne*, based on its citation to Cipla's Answering Brief, D.I. 14. D.I. 23 at 7 n.6. But again, the defendant in that case did seek application of higher standard, which was rejected. *Shure Inc.*, 2020 WL 2839294, at *5 n.12. Read in context, the reply brief's footnote reads as Ipsen distinguishing itself by clarifying that *Ipsen* did not seek application of a higher pleading standard. D.I. 23 at 7 n.6.

Even if this Court agreed with Ipsen that it did not disclaim reliance on Rule 9, this Court would still apply Rule 8 as opposed to the heightened standard because (1) it was unclear to this Court whether Ipsen meant to argue that Rule 9(b) should be applied[2], and (2) neither the Supreme Court nor the Third Circuit has held that Rule 9(b) is the appropriate standard for Lanham Act claims. *See, e.g.*, *Peloton Interactive, Inc. v. ICON Heath & Fitness, Inc.*, C.A. No. 20-662-RGA, 2021 WL 2188219, at *5 (D. Del. May 28, 2021) (examining Lanham Act counterclaims under Rule 8 as opposed to a "heightened standard").

Accordingly, having reviewed the record *de novo*, the Court agrees with the Report's conclusion that Cipla sufficiently pled its claim under the Lanham Act. Thus, Ipsen's objections to the Report are overruled.

E. Counts II-V Are Not Preempted

This Court agrees that Cipla's state-law claims are not preempted by federal law.[3] Ipsen argues "federal law—not state law—is the exclusive vehicle for analyzing the propriety of one

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[2] In its initial briefing for the Motion, Ipsen had only expressly referred to Rule 9(b) in footnotes. *See* D.I. 17 at 15 n. 17; D.I. 23 at 7 n. 6. First, in its Opening Brief, Ipsen correctly notes that the Third Circuit has not decided the issue of whether Lanham Act false advertising claims must satisfy Rule 9(b), but then goes on to say that Cipla "do[es] not satisfy the traditional pleading standard, let alone that of Rule 9(b)." D.I. 17 at 15 n.17. In its reply brief, Ipsen discusses Rule 9(b) to distinguish a case cited by Cipla to show that, in the cited case, the moving party did not invoke the heightened pleading standard. D.I. 23 at 7 n.6.

[3] Pursuant to 28 U.S.C. § 636(b)(1), the Court need not review unobjected-to portions of magistrate judges' reports and recommendations. As there were no objections to Section III.E of

HCPCS code versus another" and "CMS has exclusive authority to set HCPCS codes, leaving no room for states to create potentially inconsistent obligations." D.I. 65 at 8-9. As explained above, *see supra* §§ III.B, III.D, Cipla's claims do not ask the Court to reconsider the coding determinations. D.I. 65 at 1 ("Cipla does not challenge, directly or indirectly, the regulatory decisions of either agency."). The state law counts are deceptive trade practices under the Delaware Uniform Deceptive Trade Practices Act, unfair competition, tortious interference with economic advantage, and trade libel under Delaware common law. D.I. 1 ¶¶ 69-99. Cipla's Complaint does not require this Court to "intrude on the exclusive authority of CMS or the FDA[,]" but to separately review Ipsen's, not CMS's, alleged statements and determine if those statements violate state law. D.I. 64 at 15. This Court agrees that "Ipsen's argument for preemption is again based on its mischaracterization of the complaint and insistence that Cipla's claims require the court to substitute its judgement for CMS," and that neither field nor conflict preemption bars Cipla's claims. D.I. 64 at 15.

Accordingly, having reviewed the record *de novo*, the Court agrees with the Report's conclusion that Cipla's state-law claims are not preempted. Thus, Ipsen's objections to the Report are overruled.

F. The Primary Jurisdiction Doctrine Is Not a Basis to Dismiss the Complaint

Lastly, Ipsen argues that the Complaint should be dismissed under the primary jurisdiction doctrine. The Third Circuit advises analyzing the following four factors when asking if a court should abstain on primary jurisdiction grounds. *Baykeeper v. NL Indus., Inc.*, 660 F.3d 686, 691 (3d Cir. 2011). Those factors are:

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the Report concluding that Cipla adequately pled its state-law claims, D.I. 64 at 15-17, this Court, having reviewed for clear error, will adopt that portion of the Report in full. *See Guardant Health, Inc. v. Found. Med., Inc.*, C.A. No. 17-1616-LPS-CJB, 2020 WL 5994155, at *3 (D. Del. Oct. 9, 2020).

> (1) Whether the question at issue is within the conventional experience of judges or whether it involves technical or policy considerations within the agency's particular field of expertise; (2) Whether the question at issue is particularly within the agency's discretion; (3) Whether there exists a substantial danger of inconsistent rulings; and (4) Whether a prior application to the agency has been made.

Id. (quoting *Global Naps, Inc. v. Bell Atl.–N.J.*, 287 F. Supp. 2d 532, 549 (D.N.J. 2003)).

None of the factors weigh in favor of abstention. Because the Complaint does not ask this Court to determine HCPCS coding, the first two factors weigh against abstention. With respect to factors three and four, Ipsen has failed to address why there would be a substantial danger of inconsistent rulings and/or whether a prior application to an agency has been made.

Accordingly, having reviewed the record *de novo*, the Court agrees with the Report's conclusion that the primary jurisdiction doctrine does not preclude Cipla's claims. Thus, Ipsen's objections to the Report are overruled.

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NOW THEREFORE, IT IS **HEREBY ORDERED** on June 15, 2023 that:

1. Ipsen's Objections (D.I. 65) to the Report are **OVERRULED**;

2. The Report is **ADOPTED**.

GREGORY B. WILLIAMS
UNITED STATES DISTRICT JUDGE